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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,619	01/22/2002	Richard J. Melker	UF-270	5786

23557 7590 04/08/2003

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EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,619	MELKER ET AL.	
	Examiner	Art Unit	
	Navin Natnithithadha	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *35-39* is/are allowed.

6)☒ Claim(s) *1,2,5-7,15,18-20,22,23,25,33 and 34* is/are rejected.

7)☒ Claim(s) *3,4,8-14,16,17,21,24 and 26-32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

2. The disclosure is objected to because of the following informalities:

In paragraph 7, line 2, "EEG" is an acronym that is not previously defined.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 14, 15, 18-20, 22, 23, and 25, are rejected under 35 U.S.C. 102(b) as being anticipated by Littlejohn, U.S. Patent No. 3,649,199 A.

In regards to claim 1, Littlejohn teaches a method for determining the depth of anesthesia wherein at least one anesthetic agent is administered into a

patient's bloodstream during the delivery of anesthesia (see column 4, lines 41-48), comprising: sampling a patient's expired breath (see column 1, lines 56-59); analyzing the breath for concentration of at least one substance indicative of the anesthetic agent using sensor technology (see column 1, lines 39-47); and determining depth of anesthesia based on the concentration (see column 4, lines 39-48).

As to claims 2, 18, and 19, Littlejohn teaches the breath is analyzed after a predetermined period of time (see column 1, lines 48-52 and column 4, lines 31-32).

As to claim 15, Littlejohn teaches the concentration is measured to determine anesthetic blood concentration (see column 4, lines 32-42).

As to claim 20, Littlejohn teaches the patient's breath is analyzed by a mass spectrometer 21.

As to claims 22 and 23, Littlejohn teaches recording and transmitting (i.e. monitoring by an anesthesiologist) data resulting from analysis of the patient's breath (see column 4, lines 39-49).

As to claim 25, Littlejohn teaches collecting a gas sample prior to analysis (see column 1, lines 41-43).

4. Claims 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Gustafsson, U.S. Patent No. 5,447 165, A.

In regards to claims 33 and 34, teaches a method for monitoring endogenous compounds (i.e. nitrogen monoxide) in a patient, including: sampling a patient's expired breath (see column 5, lines 42-44); analyzing the breath for concentration of endogenous compounds using sensor technology (see column 5, lines 51-61); and calculating the concentration of endogenous compounds (see column 8, lines 1-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Littlejohn, U.S. Patent No. 3,649,199 A.

Littlejohn teaches claim 1 as discussed above. As to claims 5-7, Littlejohn does not specifically teach the agent is delivered by a delivery method selected from the group comprising: intravenous delivery, parenteral delivery, sublingual delivery, transdermal delivery, i.v. bolus delivery, continuous infusion, and an infusion pump. However, Littlejohn does disclose "the anesthesiologist would administer anesthetic to the patient while monitoring the amount of anesthetic...". He clearly suggests delivering an agent to the patient, and therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to administering anesthetic to the patient by a specific delivery method.

Allowable Subject Matter

6. Claims 35-39 allowed.

7. Claims 3, 4, 8-14, 16, 17, 21, 24, and 26-32, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter:

As to claim 3, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including using a flow sensor with the Littlejohn's invention.

As to claim 4, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including controlling an infusion pump.

As to claim 8, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including an agent selected from the group comprising Remifentanil and Propofol.

As to claim 9, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including the steps are repeated periodically to monitor trending over time.

As to claims 10-13, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including an agent is for amnesia, analgesia, muscle relaxation, or sedation.

As to claim 14, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including a combination of agents is administered.

As to claim 16, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including the concentration is measured to determine analgesic blood concentration.

As to claim 17, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including the concentration is measured for a level indicative of recovery.

As to claim 18, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including

As to claim 21, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including the sensor technology produces a unique electronic fingerprint to characterize the concentration of at least one substance.

As to claim 22, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including

As to claim 24, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including comparing the substance sensed in the patient's breath with a predetermined signature profile.

As to claim 26, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including dehumidifying the patient's breath prior to analyzing.

As to claim 27, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including detecting exhalation of the patient's breath with a sensor.

As to claims 28-30, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including the substance indicative of the anesthetic agent is free anesthetic agent and/or metabolites of the anesthetic agent.

As to claims 31 and 32, the prior art does not teach a method of determining the depth of anesthesia as claimed in claim 1 including assigning a numerical value to the concentration as analyzed upon reaching a level of anesthetic effect in the patient and, assigning higher or lower values to the concentration based on its relative changes.

In regards to claims 35-37, the prior art does not teach an anesthetic agent delivery system for delivering a desired does of anesthetic agent to a patient including: a breath analyzer for analyzing the patient's breath for concentration of at least one substance indicative of the anesthetic agent concentration in the patient's bloodstream that provides a signal to indicate the anesthetic agent concentration delivered to the patient; and a system controller connected to an anesthetic supply which receives the signal and controls the amount of anesthetic agent based on the signal.

In regards to claim 38, the prior art does not each an apparatus for administering intravenous anesthesia to a patient including: a breath analyzer for analyzing the patient's breath for concentration of at least one substance indicative of the anesthetic agent in the patient's bloodstream that provides a signal to indicate the anesthetic agent concentration delivered to the patient; and a system controller connected to an

anesthetic supply which receives the signal and controls the amount of anesthetic agent based on the signal.

In regards to claim 39, the prior art does not teach a method for monitoring perflubron levels in an anemic patient, including: analyzing the breath for concentration of perflubron using sensor technology; and calculating the blood concentration of perflubron based on the concentration.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (703) 305-2445. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3591 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Navin Natnithithadha
Patent Examiner
GAU 3736
April 3, 2003